AMERICAN ASSOCIATION OF BLOOD BANKS

America's Blood Centers

American Red Cross

July 26, 2002

Bar Code Label Requirements for Human Drug Products

Statement of
American Association of Blood Banks, America's Blood Centers and American Red Cross

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Docket

The American Association of Blood Banks (AABB) is the professional society for over 8,000 individuals involved in blood banking and transfusion medicine and represents approximately 2,000 institutional members, including blood collection centers, hospital-based blood banks, and transfusion services as they collect, process, distribute, and transfuse blood and blood components and hematopoietic stem cells. Our members are responsible for virtually all of the blood collected and more than 80 percent of the blood transfused in this country. For over 50 years, the AABB's highest priority has been to maintain and enhance the safety and availability of the nation's blood supply.

America's Blood Centers (ABC) is an international network of community-based blood centers that collects nearly half of the U.S. blood supply and about 25% of the Canadian blood supply. The largest provider of blood components and services, America's Blood Centers' members are located in 45 states, serving more than 125 million people at 450 blood donation sites. For 40 years, America's Blood Centers' members have been committed to serving the needs of their local communities by saving lives through volunteer blood donation.

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The American Red Cross (ARC) is an independent, non-profit organization dedicated to saving lives, easing suffering and restoring hope at home and around the world. The Red Cross, through its 36 Blood Services regions, supplies approximately half of the nation's blood for transfusion needs. Its primary focus is providing high quality blood and blood products to the patients who need them, but ARC is also a large supplier of human allograft tissue including heart valves, skin, bone and associated connective tissues. Additionally, the Red Cross is engaged in research and other efforts to support donation and

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processing of such human derived products as umbilical cord blood and bone marrow for use in treatment of malignancies and other serious diseases.

The American Association of Blood Banks, America's Blood Centers and American Red Cross agree that medication errors are a serious concern and are pleased to see that the Food and Drug Administration (FDA) is addressing the issue. Since blood and blood components are classified as both a drug and a biologic, the AABB, ABC and ARC are very interested in plans to consider the development of a regulation on bar code labeling for human drug products, including biologics.

The primary problem that must be addressed in transfusion medicine is reduction of human error. The AABB, ABC and ARC believe that the introduction of new technologies, such as bar coding or other systems or symbologies, aimed at reducing the risk of human error can save patient lives.

The blood banking community suggests that the FDA adopt a broad systems approach to the issue of minimizing the need for human interface. Mandating the use of bar codes without also considering how the bar code can be read and how it will be utilized within the various hospital systems will not reduce human error. And, while bar codes may offer one approach to reducing transfusion errors, the FDA must not codify policy that would limit the use of other equally effective technologies, such as radio frequency tags. **The important issue is not to mandate the particular symbology to be used. Rather, FDA and providers should focus on requiring electronic data interchange and the definition and use of standard data structures. In addition, any system developed for patient and product identification for drugs and pharmacies must also be compatible with blood and transfusion services.**

Bar Coding of Blood Products

In answer to the questions posed in the June 18, 2002, *Federal Register* notice, the AABB, ABC and ARC note that blood and blood components are already barcoded. Codabar has been in use since the 1980s. A newer bar code, ISBT 128, has been successfully introduced in other countries and is currently under consideration in the US. The FDA endorsed ISBT 128 in a guidance document published June 6, 2000, *Guidance for Industry: Recognition and Use of a Standard for the Uniform Labeling of Blood and Blood Components*. It is expected that the 22nd edition of the AABB *Standards for Blood Banks and Transfusion Services*, will require ISBT Code 128, if a facility is to remain accredited by the AABB.

Since many of the considerations discussed in its design are also under consideration at this public meeting, the following description of ISBT 128 labeling and the attached sample label provide useful information.

ISBT 128 is an international standard for the data associated with blood transfusion and stem cell and tissue transplantation. It provides for a globally unique donation numbering system, internationally standardized product definitions and standard data structures for bar coding and electronic data interchange (EDI).

ISBT 128 utilizes Code 128 symbology, but is also capable of using other formats (e.g., other bar codes, two-dimensional bar codes or radio frequency tags) for transferring information electronically. Code 128 symbology was chosen for the following reasons:

1. It is highly accurate. By use of multiple check digits, including ones to verify the accuracy of keyboard entries, accurate data entry is assured.
2. Concatenation is allowed. Concatenation is a method by which two bar codes can be read as if they were a single bar code. This provides a means for checking one bar code against the other to see that both are in place. It further ensures that data that are interdependent (such as the unit identification number and ABO/Rh type or the product code and expiration date/time) can be scanned together to prevent errors caused by staff scanning label elements separately. Such errors could occur, for example, if a staff member scanned a unit identification number on one blood component, was interrupted, and then scanned the ABO/Rh label of the next blood component to be label-verified. Errors can obviously occur if staff associates the unit identification number of one blood component with the ABO/Rh of another.
3. High-density printing is allowed. When a great deal of information must be encoded, and limited space is available for the label, Code 128 allows double density printing. This allows large amounts of data to be printed on small labels.
4. Code 128 is a common symbology. Most printers are capable of printing it and most scanners are capable of reading it.

ISBT 128 coding provides blood, hematopoietic progenitor cell and tissue transplantation centers with many advantages. These include:

1. **Internationally agreed upon placement of labeling information**

   The placement of information on a container of blood, hematopoietic progenitor cell or tissue products is standardized. (See attached example of blood label.) This ensures that regardless of where a product is collected and where it is used, the end-user (physician or nurse) knows exactly where to find the necessary information.

2. **Internationally unique numbering system for blood, hematopoietic progenitor cell and tissue donations**

   As each blood, hematopoietic progenitor cell or tissue donation is made, it is given a unique number that identifies the facility at which the donation occurred, the year and day that it was donated, and a serial number. By incorporating the facility, date of collection and a serial number into the product identification number, the number is unique and can repeat itself only every 100 years, which is well beyond the storage period for blood, stem cell or tissue donations. This unique identification number allows the transfer of blood, hematopoietic progenitor cells and tissue products throughout the US and the world without having to assign local numbers because of possible duplication. By avoiding the assignment of local identification numbers (renumbering the product), traceability of the product from donor to patient is assured.

3. **Internationally standardized product codes**

   Over 4000 codes have been developed to uniquely and clearly define blood, hematopoietic progenitor cell and tissue products. The code is easily expandable as new products are defined. By standardizing these codes through international consensus, sharing of precious resources is allowed while avoiding obstacles caused by writing on labels in different languages. In addition, where needed or desirable, these data structures encode product potency (e.g., range of platelets present in the product). This is analogous to defining the dose for drug products.

4. **Encoding of date and time of collection, production and expiration**
   The dates and times critical to the product (collection, production and expiration) can be encoded.

5. **Encoding of special testing results**
   The results of specialized testing (e.g., CMV, red cell or HLA phenotype) of the product can be encoded onto the label. Following transfer of laboratory results from an analyzer into a computer system (or data entry, if tests are performed manually), bar-coded labels (or other electronically scannable labels) can be generated without the need of human transcription and its inherent risk of errors. Currently, under the older Codabar system used in the US, such information is handwritten onto labels. Not only is there risk of transcription errors, but also the legibility of handwriting is a problem.

6. **Encoding of the manufacturer, catalog number and lot numbers of blood, hematopoietic progenitor cell or tissue containers**
   Because it is essential to be able to trace the containers in which blood, hematopoietic progenitor cell or tissue products are prepared, this information is also encoded into an electronically scannable format on the label. This information can then be scanned accurately into the computer system of the collection facility. Given the length of many lot numbers, scanning of these numbers is the only way to ensure accuracy of records.

7. **Mechanism for maintenance and growth of standard**
   Finally, a major benefit of ISBT 128 is that there is a mechanism for continued maintenance and growth. This is accomplished through the International Council for Commonality in Blood Banking Automation (ICCBBA), a not-for-profit entity incorporated in Virginia in 1995. Funded by user fees, the ICCBBA holds regular international meetings to develop consensus on issues related to the creation and maintenance of codes necessary for information transfer related to blood, hematopoietic progenitor cell and tissue products.

The AABB, ABC and ARC believe that the advantages described above warrant movement to a system where all blood components in the United States are packaged with ISBT 128 or comparable labeling. Such a system will reduce the risk of human error and improve patient safety for individuals receiving transfusions.

Additional Technologies Needed to Prevent Mistransfusion of Wrong Unit of Blood

Currently, the bar-coded information on a blood product is used by the blood collection facility to identify the exact product, to track manufacturing steps and to ship the product to hospitals for use. Within the hospital transfusion service, the bar-coded information is used to identify the manufacturer and the product and to determine which product is assigned to a particular patient. However, more needs to be done to ensure that the right patient receives the right product.

Transfusion of incompatible blood, or mistransfusion of blood, is the most common cause of serious morbidity and mortality related to transfusion. Serious errors are made at the time of sample collection, within the laboratory, at the moment of blood issue from the laboratory, and at the bedside. ABO-

incompatible transfusions due to the misidentification of recipients at the time of transfusion are the *reported* cause of fatality for as many as two dozen patients each year in the US. It is believed that such mistransfusions are underreported. (Linden JV, Wagner K, Voytovich AE, Sheehan J Transfusion errors in New York State: an analysis of 10 years' experience. *Transfusion* 2000; 40:1207-13. Sazama K. Reports of 355 transfusion-associated deaths: 1976 through 1985. *Transfusion* 1990; 30:583-90)

The AABB, ABC and ARC strongly encourage research, development and widespread application of new technologies aimed at ensuring the right patient gets the right unit of blood. Some such technologies, including certain methods of computerized bar coding and patient wrist bands, are already being introduced in individual hospitals. Unfortunately, there has been only limited application of existing technology to reduce mistransfusion, overtransfusion and undertransfusion. This inadequate use of existing technologies in the US is most likely the result of the existing reimbursement system, under which blood is not separately coded and reimbursed. This system operates as a disincentive to the development and application of new technologies in blood transfusion. This problem must be addressed if patients are to have access to and obtain the benefits of new technology.

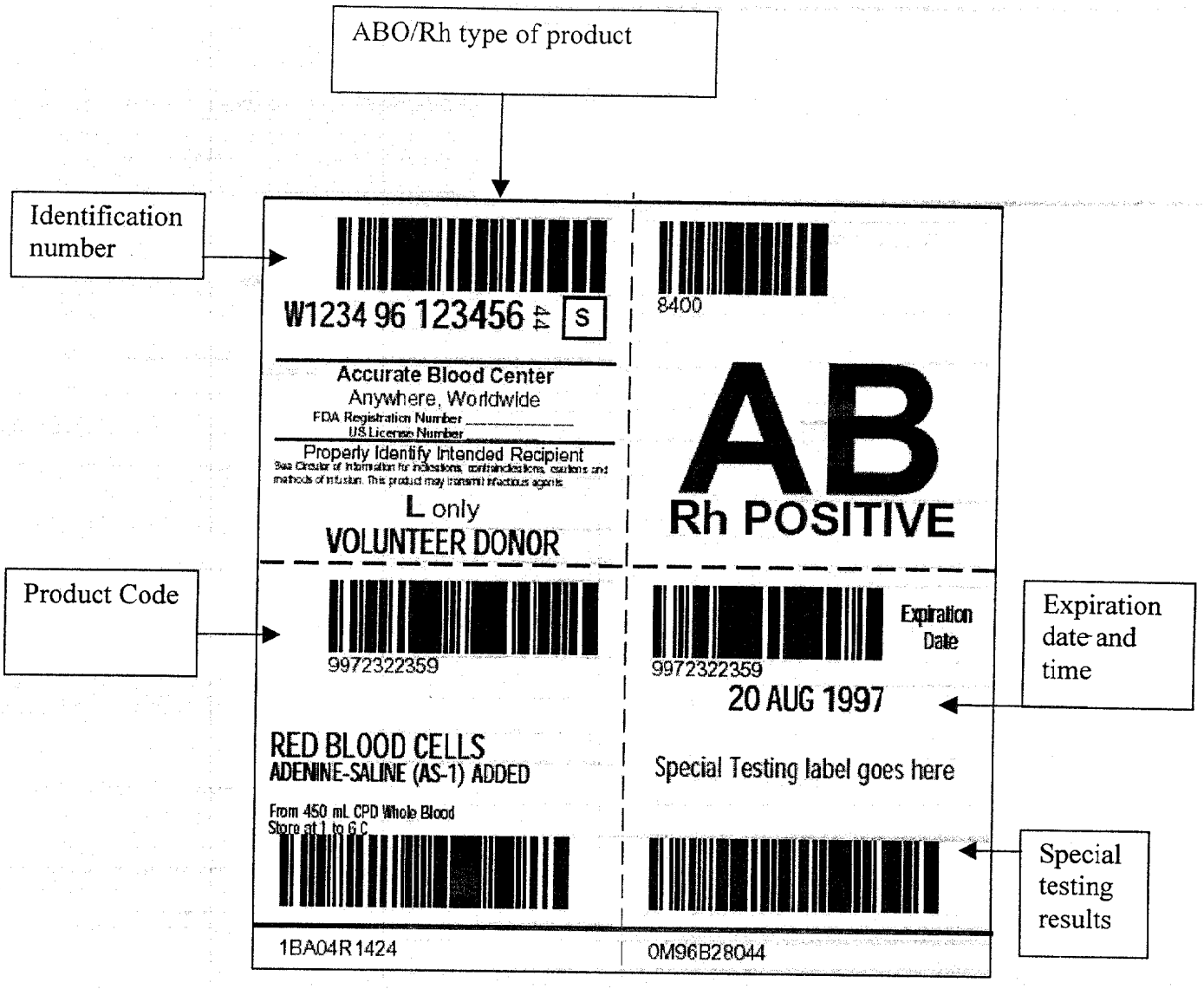
The entire transfusion medicine community — government and private — must move forward to encourage the use of such promising technologies designed to avoid patient harm. Whatever system is devised for patient and product identification systems for drugs and pharmacies must also be applicable to blood and transfusion services.

In summary, the AABB, ABC and urge FDA to:

1. Require the blood banking community to adopt the United States Industry Consensus Standard for the Uniform Labeling of Blood and Blood Components. This standard would currently mandate bar codes using ISBT 128 symbology, but is readily adaptable to change.

2. Encourage the development and use of patient and product identification systems for blood products that are compatible with drug and pharmacy systems.

The AABB, ABC and ARC welcome the opportunity to work with the FDA and other interested parties in advancing our common goal of enhancing patient safety through the use of beneficial technologies.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Anywhere, Worldwide
FDA Registration Number
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